

EXHIBIT D

Elizabeth Mueller, MD, MSME, FACS

1 IN THE UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

3 -----)
4 IN RE: ETHICON, INC.,) Master File No.
5 PELVIC REPAIR SYSTEM) 2:12-MD-02327
6 PRODUCTS LIABILITY)
7 LITIGATION) MDL 2327
8 -----)
9) JOSEPH R. GOODWIN
10 THIS DOCUMENT RELATES TO) U.S. DISTRICT JUDGE
11 ALL WAVE 4 AND SUBSEQUENT)
12 WAVE CASES AND)
13 PLAINTIFFS:)
14)
15 Connie Thate)
16 Case No. 2:12cv04144)
17 -----)

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 GENERAL EXPERT DEPOSITION OF
ELIZABETH MUELLER, M.D., MSME, FACS
 TVT and TVT-O

 March 11, 2017
 Rosemont, Illinois

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Elizabeth Mueller, MD, MSME, FACS

1 Exact?

2 A. Yes.

3 Q. Are you able to split, you know, give me
4 a number for each?

5 A. No.

6 Q. What do you currently use?

7 A. TVT Exact.

8 Q. Why do you use TVT Exact over the TVT
9 original?

10 A. Well, I like the smaller -- I like the
11 smaller introducer.

12 Q. So, the smaller trocar?

13 A. The smaller trocar.

14 Q. What is the diameter of the trocar for
15 the TVT Retropubic original?

16 A. I have no idea.

17 Q. And the TVT Exact is a 3 millimeter
18 trocar, is that correct?

19 A. It sounds right.

20 Q. Would the TVT Retropubic trocar be
21 around 4 to 5 millimeters? A fair estimate?

22 MS. SCHMID: Objection; foundation. Go ahead.

23 BY THE WITNESS:

24 A. I don't know. I think it's a little bit

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1 TVT Retropubic slings, do you do it under general
2 anesthesia?

3 A. It depends.

4 Q. Do you do it under just local sometimes?

5 A. Never.

6 Q. So, when you say "It depends," what do
7 you mean by that?

8 A. Well, there is spinal anesthesia, too.

9 Q. So, you either use spinal or general
10 anesthesia?

11 A. That's correct.

12 Q. And what about local, do you do local in
13 addition to spinal?

14 A. Yes.

15 Q. And general?

16 A. Yes.

17 Q. Doctor, I know that in your report you
18 talk about mechanically-cut mesh as well as
19 laser-cut mesh.

20 Do you know how many mechanically-cut
21 mesh that you've implanted?

22 A. No.

23 Q. What about the laser-cut mesh?

24 A. No.

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1 Q. Do you have a percentage between the
2 two?

3 A. No.

4 Q. So, you don't make a concerted effort to
5 determine which kind of mesh you're implanting?

6 A. You know, there is not a thing in the
7 literature that suggests that that makes any
8 difference. So, no, that's not something that I
9 look at.

10 Q. Doctor, would you -- do you believe that
11 mechanically-cut mesh can fray prior to
12 implantation?

13 A. I don't -- I don't have that much of an
14 opinion on it.

15 Q. When you implanted the mechanically-cut
16 mesh, was it clear or blue?

17 A. I don't remember.

18 MS. SCHMID: If you know.

19 BY MS. LIU:

20 Q. Currently the mesh that you're
21 implanting is blue, is that correct?

22 A. That's correct.

23 Q. Do you remember implanting clear mesh?

24 A. I -- I'm -- I don't know.

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1 that's, you know -- the plastic that's around it.
2 And I implant those myself. I haven't seen blue
3 particles when I pull the sheaths out. So, I
4 haven't seen blue particles.

5 Q. And, Doctor, you say that you have been
6 using TVT Exact pretty much since it came out, is
7 that correct?

8 A. I don't know. I don't know when it was,
9 so I can't say if it's when it came out.

10 Q. And the TVT Exact uses the laser-cut
11 mesh, is that correct?

12 A. You would have to tell me.

13 MS. SCHMID: Objection; foundation.

14 BY THE WITNESS:

15 A. You would have to tell me that. I
16 don't.

17 BY MS. LIU:

18 Q. So, you're not aware of whether or not
19 the TVT Exact uses laser-cut mesh or
20 mechanically-cut mesh?

21 A. No.

22 Q. And, Doctor, I want to go through the
23 process of how the mesh is handed to you.

24 You mentioned once it's taken out of the

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1 meant for you to use different
2 introducers than the ones that's
3 attached, is it?)

4 BY THE WITNESS:

5 A. I guess not. I don't -- I don't
6 understand what this is about. I'm not -- I have
7 placed the sling every day.

8 I am, by the way, an engineer and have a
9 Master's Degree in engineering.

10 All I do is pass the sling behind the
11 pubic bone.

12 BY MS. LIU:

13 Q. And, Doctor, I'm just asking some
14 questions about whether or not, since -- okay.
15 Let's strike that.

16 Doctor, you're -- you have a Master's
17 Degree in engineering, correct?

18 A. That's right.

19 Q. And as far as an engineer goes, have you
20 ever designed a trocar?

21 A. No.

22 Q. And if you could design a trocar,
23 Doctor, would you use your own trocar, take the TVT
24 mesh off of the trocar that it's attached to and

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1 in mechanical engineering, correct?

2 A. That's right.

3 Q. Doctor, when you -- strike that.

4 How many years did you work as an
5 engineer?

6 A. Six.

7 Q. And based on your report, it looks like
8 you were a manufacturing engineer, is that correct?

9 A. No. I was a manufacturing manager, but
10 I had specific engineering responsibilities.

11 Q. And as far as the engineering
12 responsibilities go, was it more from a production
13 standpoint or design standpoint?

14 A. It was from a production standpoint.

15 Q. Did you design any products during your
16 time as an engineer?

17 A. No.

18 Q. And, Doctor, with your engineering
19 background, have you designed any mesh devices?

20 A. No.

21 Q. And when you were an engineer, was it an
22 engineering in a medical device product?

23 A. No.

24 Q. What was the product that you were

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1 working on?

2 A. It was dishwashing -- Cascade -- it was
3 for Procter & Gamble. So, I worked in high-speed
4 manufacturing.

5 Q. And it was, you said, Cascade
6 dishwashing liquid?

7 A. That was the final job.

8 Q. Was it with Procter & Gamble your entire
9 career as an engineer?

10 A. That's correct.

11 Q. So, Doctor, you don't have any
12 experience designing mesh products, is that
13 correct?

14 A. No, I don't.

15 Q. Doctor, have you only ever used the
16 Gynecare TVT products for slings?

17 A. No. I think there was -- I just said
18 that, that there was a period in which we didn't
19 use Gynecare products for slings. I don't remember
20 what was the manufacturer. It was a short-lived
21 experience at Loyola, and it had to do with cost
22 concerns when we were bought by Trinity.

23 Q. Do you remember how long ago this was?

24 A. I don't.

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1 might be a recurrence and someone would have to do
2 another surgery that's close by.

3 So, I just choose not to use it then.

4 Q. And, Doctor, you've reviewed the IFU for
5 the TVT Retropubic, is that correct?

6 A. You know, I don't typically review IFUs.
7 So, I can't ever remember -- I remember the first
8 time that I wrote an operative note. I went
9 through the IFU just looking at it, but that wasn't
10 how I decided to put the sling in.

11 So, I don't typically read IFUs, no.

12 Q. And, Doctor, did you review the IFU
13 prior to putting together your expert report?

14 A. There was -- I glanced at a couple IFUs.
15 But, again, I -- I was going to read it. I know
16 that that's one of the big legal issues. But then
17 I thought I would just reflect what truly has been
18 my practice, that I don't read device IFUs.

19 I base my decisions off of the way I was
20 taught, the way I teach, and the clinical trials
21 I've participated in.

22 Q. Doctor, do you know whether it is a
23 contraindication in the IFU that somebody has had a
24 tumor at the bladder neck or any of those other

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1 procedures that you had described as
2 contraindicated for the TVT sling?

3 MS. SCHMID: Objection; form, foundation. Do
4 you have a copy of the IFU for the doctor?

5 MS. LIU: I do not.

6 MS. SCHMID: Okay.

7 BY THE WITNESS:

8 A. I don't know.

9 BY MS. LIU:

10 Q. And, Doctor, so, in drafting your
11 report, you did not rely on the IFU, is that
12 correct?

13 A. No, I wouldn't rely on the IFU.

14 Q. And not even for the expert opinion that
15 you have provided?

16 A. No.

17 Q. And, Doctor, you've never drafted an IFU
18 before, have you?

19 A. No.

20 Q. Would you consider yourself an IFU
21 expert?

22 A. I don't really know what you even mean
23 by an IFU. I mean, Instructions for Use. So, no,
24 I wouldn't consider myself a -- I consider myself a

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1 surgical teacher and a teacher expert, but I'm not
2 an IFU expert.

3 Q. You've never drafted any kind of
4 labeling for a medical device --

5 A. No.

6 Q. -- is that correct?

7 A. No, I have not.

8 Q. Have you ever given any opinions to a
9 medical device company as to what they needed in
10 their IFU?

11 A. No.

12 Q. Doctor, you provided two reliance lists
13 for your expert report. Do you recall that?

14 A. Yes.

15 (WHEREUPON, certain documents were
16 marked Mueller (TVT/TVT-O) Exhibit
17 No. 5, General Reliance List in
18 Addition to Materials Referenced in
19 Report, MDL Wave 4, and No. 6,
20 Supplemental General Reliance List
21 in Addition to Materials Referenced
22 in Report, MDL Wave 4.)

23 BY MS. LIU:

24 Q. Doctor, I'm handing you what I have

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1 Q. I just want to ask in general did you
2 read everything?

3 A. I didn't read everything.

4 Q. Did you read the internal documents?

5 A. I did not.

6 Q. Did you read the company witness
7 depositions?

8 A. No.

9 Q. So, would it be fair to say that you did
10 not rely on any internal company documents in
11 drafting your report?

12 A. That would be fair to say that.

13 Q. And would it be fair to say that you did
14 not rely on any of the corporate witness
15 depositions?

16 A. That's right. I did not rely on those.

17 Q. Do you know why they're on your reliance
18 list?

19 A. I suppose. I don't know.

20 Q. Doctor, do you know how the company
21 documents were selected to be provided to you?

22 A. I have -- I don't know.

23 Q. And have you reviewed any of them?

24 A. No.

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1 Q. Do you believe that companies would put
2 less information in their IFUs than what is
3 necessary?

4 A. No.

5 MS. SCHMID: Objection; form, foundation.

6 BY THE WITNESS:

7 A. No, I don't believe that. I just don't
8 believe that it's in any kind of context. So, it
9 doesn't -- physicians don't read IFUs I believe.

10 Q. And --

11 A. So, I don't -- I can't comment on what
12 should be in an IFU or what is in an IFU because
13 it's not something I'm reading. It's not something
14 I'm teaching and I'm certainly not teaching people
15 to read.

16 I'm teaching them to go to the
17 literature, read about what your -- what procedures
18 are indicated, and there is plenty of literature
19 for us to understand what to do for patients.

20 Q. Now, you stated that you started using
21 slings for this TOMUS trial, correct?

22 A. That's correct.

23 Q. And you never used them prior to the
24 TOMUS trial?

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1 A. No, no.

2 Q. Doctor, do you believe that the TVT
3 sling can degrade?

4 A. No.

5 Q. And how have you come to that
6 conclusion?

7 A. I've come to that conclusion based on
8 work.

9 So, when we started, when Dr. Brubaker
10 was over at Rush, this was before I was even in the
11 fellowship program, they were always using fascial
12 slings for sacral colpopexy. Well, they were using
13 mesh for sacral colpopexy and they were using
14 fascial slings for -- they were using fascial
15 slings for stress incontinence.

16 I'm sorry. I'm just fading a little
17 bit.

18 And, so, they went to a meeting and they
19 found that people were using cadaveric tissue to do
20 slings and to do sacral colpopexy.

21 So, Dr. Brubaker, based on that data,
22 changed her practice and put in something like 35
23 slings that were cadaveric and put in a bunch of
24 sacral colpopexies that were cadaveric.

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1 Q. So, Doctor, what you've described, I
2 believe, in the cadaveric slings were --

3 A. Okay.

4 Q. -- you're talking about the material
5 being absorbed into the woman's body, is that
6 correct?

7 A. I'm talking about being degraded.

8 Q. So, that's your terminology for
9 degradation?

10 A. Right.

11 Q. So, if the surface of the TVT is cracked
12 or peeled or blistered, do you consider that to be
13 degradation?

14 MS. SCHMID: Objection.

15 BY THE WITNESS:

16 A. No.

17 MS. SCHMID: Form.

18 BY THE WITNESS:

19 A. First, we don't see that. When we take
20 a look at electron microscopy images where instead
21 of leaving the little protein coating that's on --
22 you know, if you spit on something and if you spit
23 on like plastic and it dries, there is a film on
24 it. That doesn't mean that the plastic has made

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1 that itself. If you wash that off, then it's gone.

2 And there is nice images that show that
3 that little protein layer is what people thought
4 was disintegrating and actually the mesh is intact.

5 So, no, I don't believe that it's
6 disintegrating or degrading, excuse me, was the
7 word you used.

8 Q. Have you looked at explanted mesh under
9 microscope?

10 A. I haven't.

11 Q. So, you haven't cleaned the mesh to look
12 at it, correct?

13 A. Well, I would have to say that it
14 wouldn't be something -- we can't appreciate on
15 your version of degradation under a microscope. It
16 has to be done under an electron microscope. Not
17 even a microscope sees what you're talking about.

18 So, when you look at images of electron
19 microscopy where the mesh has been put into
20 solutions that degrade, that protein layer, we see
21 an intact mesh.

22 Q. And, Doctor, do you believe that the TVT
23 sling is an inert material?

24 A. Yes.

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1 Q. And that's why you also don't believe
2 that it degrades, is that correct?

3 A. Yes.

4 Q. Do you know whether or not there are
5 antioxidants added to the TVT prior to its
6 manufacture?

7 A. I don't --

8 MS. SCHMID: Objection; foundation.

9 BY THE WITNESS:

10 A. I don't know if there is antioxidants
11 added.

12 BY MS. LIU:

13 Q. So, you've never -- you've never come
14 across materials that say that there are
15 antioxidants that are added to the TVT, correct?

16 MS. SCHMID: Same objection. Go ahead.

17 BY THE WITNESS:

18 A. No.

19 BY MS. LIU:

20 Q. Now, if there are antioxidants added to
21 the TVT to prevent it from, as you would call it,
22 degrading or from it having an inert property,
23 would you be concerned with what those antioxidants
24 are?

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1 MS. SCHMID: Objection; form, foundation.

2 BY THE WITNESS:

3 A. No. Again, when I put Prolene sutures
4 in people or when I use a Prolene mesh and I go
5 back later or I'm taking it out or I'm visualizing
6 it on ultrasound, I'm not seeing degradation,
7 curling, coiling, unbraiding, all of those things.

8 So, while they might be phenomena that
9 happen in a laboratory, they might be phenomena
10 that people are pontificating around, when it comes
11 to clinical trials and taking care of women, these
12 are not the things that are making an impact and
13 results.

14 We never looked at the fascial sling
15 like this. We never looked at the Burch
16 urethropexy, which, by the way, used Gore-Tex
17 sutures and Prolene sutures.

18 So, when we look at surgical outcomes,
19 these are not factors that are making a difference.

20 Q. Now, Doctor, we've established earlier
21 that when you did your ultrasounds, you did not
22 measure the width of the sling in the retropubic
23 space, correct?

24 A. That's correct.

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1 statistically significant difference. But not now.

2 Q. Doctor, do you know whether or not
3 Ethicon internally thought about putting out a
4 lighter weight mesh?

5 A. I have no idea.

6 MS. SCHMID: Objection; form, foundation.

7 BY THE WITNESS:

8 A. Yeah, I've already testified that I did
9 not read any of the internal documents. So, I have
10 no sense of what the internal workings have been of
11 Ethicon.

12 BY MS. LIU:

13 Q. Do you know whether or not in your
14 discussions in the past with Ethicon that they
15 believed that the polypropylene was not inert?

16 MS. SCHMID: Objection; form, foundation.

17 BY THE WITNESS:

18 A. I'd like to -- I don't know what you
19 mean by my discussions with Ethicon. I've never
20 been a consultant with Ethicon.

21 I've never talked with them about their
22 product other than conversations at conventions
23 where I am having a drink and barely paying
24 attention to what anybody is saying besides myself.

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1 product, correct?

2 A. Never.

3 Q. Now, Doctor, why did you not review any
4 of the internal documents in drafting your paper?

5 A. You know, I felt when I sat down and
6 started this work and I was going to make comment
7 about the care of patients and what was happening
8 to them, that I could only stay within the realm of
9 what is my experience and understanding and that
10 that's what I was being asked to do.

11 I can't possibly understand what those
12 documents mean or what in context they are.

13 I can understand this world. This is my
14 world. This is the world I publish in. This is
15 the world I talk in. These are the patients I am
16 treating and caring for.

17 So, I kept my understanding to the world
18 I live in, and I think that's important.

19 Q. And you don't believe that the people
20 who actually designed or tested the product, their
21 input would make any difference in your opinion?

22 A. Well, I'm being deposed as an expert
23 witness and the only expert part of me is the
24 doctor part of me. All that other stuff, I'm not

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1 an expert on. I don't even understand it when I'm
2 reading it.

3 So, I would help no one. I wouldn't
4 help you in your case. I certainly wouldn't help
5 Ethicon in their case by what are my
6 interpretations. I have no idea what I'm reading.

7 Q. So, anything dealing with the design,
8 the pore size, the weight, none of that is in your
9 purview, is that correct?

10 A. That's correct, because what I'm looking
11 at is when that mesh was put in patients, and we
12 look, did it help them with their symptoms and what
13 were the complications, that's all that matters to
14 me.

15 Independent of all this stuff that went
16 into the black box over here, I'm looking at what
17 was the outcome. And -- yeah.

18 Q. So, you're specifically -- your report
19 is based on clinical outcomes, your clinical
20 outcomes, is that correct?

21 A. Not my clinical outcomes. The clinical
22 outcomes of my field that's reported in the
23 international and national literature.

24 Q. Now --

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1 Q. Yes, Doctor.

2 A. Great.

3 Q. So, you never compared the differences
4 between any of the IFUs that Ethicon put out,
5 correct?

6 A. I did not, but I read the testimony of
7 other physicians who have talked about that in
8 detail.

9 Q. Now, Doctor, you also testified that you
10 have never been to any of the professional
11 education courses, correct?

12 A. I haven't been to ones where they were
13 teaching how to pass a sling. I have been, of
14 course, in the room when we are doing like, let's
15 say, an AUGS course and at an AUGS course they have
16 borrowed somebody's models or they have got
17 pelvises or they have got slings and they're right
18 next door doing something while I am teaching them
19 how to do a Burch or how to do to a ureteral
20 repair. So, those things get really fuzzy
21 sometimes, you know.

22 Q. Have you reviewed professional education
23 materials that Ethicon has put out?

24 A. No.

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1 Q. Have you heard of the Surgeon's
2 Monograph that Ethicon put out?

3 A. No. I've heard of Surgeon's Monographs
4 in general, but I haven't heard of Ethicon's or
5 read it.

6 Q. Okay. I would like you to turn to
7 page 9 of your expert report.

8 A. Yes.

9 Q. If you look at -- this is -- actually,
10 if you turn to page 8, you will see that this falls
11 under "Medical Opinions."

12 A. Yes.

13 Q. And do you see that the opinion, the
14 No. 6 opinion that you have, states, "The IFUs,
15 monographs and professional education materials for
16 TVT and TVT-O adequately and accurately reflect the
17 complications specific to the device that are
18 described in the medical literature."

19 So, Doctor, how can you make this
20 opinion when you haven't reviewed the materials?

21 A. That's true.

22 Q. So, at this point in time, Doctor, can
23 you make an opinion at all as to the materials that
24 were provided by Ethicon to the doctors as to

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1 whether or not they were sufficient?

2 A. No.

3 Q. And, Doctor, you spent a total of 19 --

4 I'm sorry. Strike that.

5 Doctor, you spent a total of 18 hours
6 preparing for the TVT and TVT-O general report, is
7 that correct?

8 A. That's true.

9 Q. And did that encompass all the time that
10 you reviewed medical literature?

11 A. Yes.

12 Q. And it included the entire time that you
13 drafted the report?

14 A. Yes, and read. I mean, you know, even
15 though they are studies I'm familiar with, to sit
16 down and read them and try to categorize or
17 hole-punch them and put them into a binder, those
18 things, things take time.

19 Q. And that was just in generating this
20 particular report?

21 A. Yes. The general report.

22 Q. And, Doctor, if you will look at your
23 report again and it's No. 7 on page 9.

24 Your opinion that there was insufficient

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1 versus laparoscopic sacral colpopexy.

2 This was a study that was awarded to Kim
3 Kenton and myself at Loyola and also to Jennifer
4 Anger at UCLA.

5 And when we sat down to start designing
6 the trial, we had to agree on a single mesh and at
7 the time we were using the Gynecare mesh. They
8 were using the Mpathy mesh. Pamela Moalli's work
9 had come out about the Mpathy mesh. And, so, we
10 just decided that we would go with what UCLA had
11 moving forward and made that transition.

12 And I haven't handled that mesh or seen
13 that mesh for years now. I mean, probably we did
14 that in, I don't remember, maybe 2009 or 2010. So,
15 I don't have much of a memory of it.

16 Q. And I believe we talked about a little
17 bit about the fact that you don't really have an
18 expertise as far as whether the TVT sling should be
19 lighter weight or larger pore, is that correct?

20 A. I don't.

21 Q. So, you don't hold yourself as a
22 materials design expert, correct?

23 A. Not on mesh, no.

24 Q. Doctor, have you heard of the TOPA mesh?

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1 A. Excuse me?

2 Q. The TOPA, T-O-P-A?

3 A. I haven't.

4 Q. Give me one second here.

5 Doctor, if you will turn to page 24 of
6 your report.

7 A. Yes.

8 Q. Do you see in the middle of that first
9 paragraph there where you --

10 MS. SCHMID: Hold on one second, counsel. I
11 just want to get to page 24.

12 BY MS. LIU:

13 Q. Are you there, Doctor?

14 A. Yes.

15 Q. Do you see the sentence where it starts
16 with "Ethicon conducted testing on a lighter
17 weight, larger pore, partially absorbable sling,
18 but it failed multiple cadaver labs"?

19 A. Yes. I didn't know the name of that was
20 TOPA.

21 Q. And, Doctor, this is -- you cite an
22 internal memo with a Bates number.

23 Now, you testified earlier that you
24 never looked at any internal documents?

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1 A. I did look at that one. I'm sorry.

2 Q. So, you did look at one?

3 A. Excuse me. I'm sorry.

4 Q. Okay. And, Doctor, do you know why
5 Ethicon was looking to develop a lighter weight
6 partially absorbable mesh?

7 MS. SCHMID: Objection; foundation.

8 BY THE WITNESS:

9 A. I don't know. But I think there was --
10 when I read in the literature about like what makes
11 the perfect mesh and what -- many people have
12 talked about an absorbable coating, that somehow
13 there was absorption, then there would be more
14 ingrowth and maybe less inflammation. So, that's
15 what I assumed.

16 I have seen that with a couple different
17 companies that have been trying to do that.

18 BY MS. LIU:

19 Q. And, Doctor, you expect to see an acute
20 chronic body -- I'm sorry. Strike that.

21 You expect to see acute inflammation
22 after placing a sling, is that correct?

23 A. I expect to see acute inflammation after
24 I do any surgery. The minute I put my scissors in